

NORBERT KOTHE ET AL.
USSN 10/030,801
Reply to Office Action dated March 29, 2004
Amendment of September 29, 2004

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

At the outset, Applicants point out that there is some confusion concerning the claims that are being prosecuted. The Office Action indicates on the Office Action Summary and then again in the first paragraph on page 2 that claims 1-29 are pending. However, the Preliminary Amendment dated January 11, 2002, requested that the examination begin based on the amended claims 1-27, i.e., as amended during the international phase. Consequently, the record needs to reflect this fact, and the prosecution should continue based on the listing of claims above, which

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derives from amended claims 1-27 resulting from the international phase.

The foregoing may require some modification of the restriction requirement. None of amended claims 1-27 claimed products. Accordingly, Applicants did not present any claims corresponding to Group II of the restriction requirement. Claim 27 corresponded to claim 29, and, thus, Group III of the restriction requirement. In short, Applicants believe there are only two groups, viz:

Group I: Claims 1-26; and

Group II: Claim 27.

The disclosure was objected to because of a typographical error in the name of the author, "Goheen," in the last paragraph on page 4. This typographical error has now been corrected.

Claim 2 was objected to for failing to limit the scope of claim 1. In response, Applicants have limited claim 2 to plasma or serum of human origin. As noted by the Examiner, claim 1 covers additionally plasma or serum of animal origin.

Claims 1, 4, 6, 12-13, 17, 19, and 21-23 were objected to for failure to indent distinct steps. In response, Applicants point out that 37 CFR § 1.75 uses the word "must" to indicate

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mandatory requirements, and "should" to indicate optional requirements, and, further, that the requirements of 37 CFR § 1.75(i) use "should," and, therefore, are optional. Applicants believe that the objected to claims are clear as now amended and that indentation would not help the presentation. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this objection.

Claims 1-26 were rejected under 35 USC § 112, second paragraph, as being indefinite. In response, Applicants have amended the claims extensively and in a manner which Applicants believe overcomes each of the Examiner's concerns. Thus, Applicants have revised the claims to use consistent terminology throughout, and have provided antecedent basis where necessary or else removed the need for antecedent basis altogether. Also, the "especially" clauses of claims 20 and 26 have been made the subject of new claims 28 and 30, respectively. Also, claim 22 has been canceled in favor of new claim 29. Finally, claim 27 has been recast as new claims 31 and 32. Although drawn to a method having a different purpose, each incorporates the processes of the elected invention, and, therefore, Applicants submit that claims 31 and 32 should be allowable if the remaining claims are found to be allowable. Accordingly, claims 31 and 32 should be considered together with the other claims. Applicants do not believe that any of the amendments introduce any new matter.

In view of the foregoing, Applicants submit that the claims are definite. An early notice

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that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

For the record, Applicants emphasize that although the claims were amended to overcome this rejection, and, therefore, might be argued to have been amended for a reason substantially related to patentability, a fair reading of the amended claims will reveal that the departures from the previous claims were for clarification purposes only, and that Applicants did not narrow the claims in any material respect. Therefore, Applicants submit that the amended claims are entitled to the full range of equivalents.

Claims 1-4, 7 and 14-15 were rejected under 35 USC § 103(a) as being obvious over Goheen et al. ("Goheen"), *J. Chromatography*, 326: 235 (1985), in view of Goudswaard et al. ("Goudswaard"), *Immunochemistry*, 14: 717 (1977). In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

According to the Examiner, Goheen teaches the present invention except that Goheen uses a linear gradient where Applicants use a step gradient. The Examiner then points to Goudswaard to show that step gradients were known in the prior art, albeit in use with a completely different type of chromatography. The Examiner concludes from this fact that it is conventional to elute a HIC column with either a linear or a step gradient, and, therefore, it would have been obvious to use a step gradient in the method of Goheen, thereby to obtain the

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present invention.

Applicants respectfully disagree that the combination of Goheen and Goudswaard makes out a *prima facie* case of obviousness. According to *Manual of Patent Examining Procedure* ("MPEP") § 2143:

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

Moreover, as reaffirmed by the Court in *In re Regel et al.*, 188 USPQ 136, 139, footnote 5 (CCPA 1975):

"The mere fact that it is *possible* to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination."

Even assuming for the sake of argument that Goudswaard shows the use of a step

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gradient in a completely different type of chromatography, the fact that step gradients were known does not, in and of itself, establish the desirability of using a step gradient in Goheen's chromatography method. The Examiner does not give any other reason why a person having ordinary skill in the art would have motivated to modify Goheen's method to incorporate a step gradient. Consequently, Applicants submit no *prima facie* case of obviousness has been made out.

Further, Applicants submit that *as a matter of law* such a person would not have been motivated. The Goheen article is discussed in the instant specification in the paragraph bridging pages 4-7. The discussion there reveals the serious drawbacks of Goheen's method, including limitation to an analytical scale process and the need to carry out the method at 0°C in order to obtain the highest resolution. The examples in the instant specification prove that the present invention overcomes these problems. There is absolutely nothing in Goudswaard that would have suggested to persons skilled in the art that use of a step gradient should solve these problems. Consequently, the present invention is characterized by unexpected benefits, which obviate any notion that the present invention would have been *prima facie* obvious from a combination of Goheen in view of Goudswaard.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered

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and withdrawn is earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

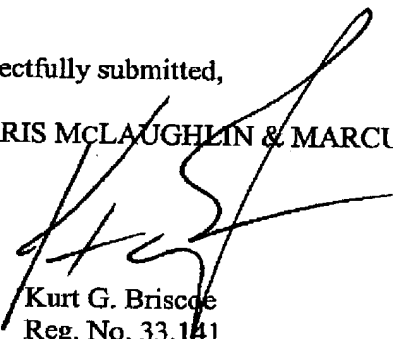
Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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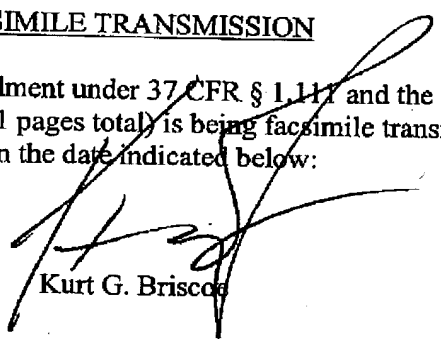
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 and the accompanying Petition for Extension of Time (21 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: September 29, 2004

By:


Kurt G. Briscoe